

**Knobbe Martens Olson & Bear LLP***Intellectual Property Law*

550 West C Street  
Suite 1200  
San Diego CA 92101  
Tel 619-235-8550  
Fax 619-235-0176  
www.kmob.com

**FACSIMILE TRANSMITTAL SHEET****CONFIRMATION COPY WILL FOLLOW VIA:**

- |  |   |
|--|---|
| <input type="checkbox"/> MAIL                  | <input checked="" type="checkbox"/> WILL NOT FOLLOW |
| <input type="checkbox"/> INTERNATIONAL AIRMAIL | <input type="checkbox"/> HAND DELIVERY              |
| <input type="checkbox"/> COURIER               | <input type="checkbox"/> WITH ENCLOSURES            |
| <input type="checkbox"/> E-MAIL                | <input type="checkbox"/> WITHOUT ENCLOSURES         |

**Confidentiality Notice:**

The documents accompanying this facsimile transmission contain confidential information which may be legally privileged. The information is intended only for the use of the recipient named below. If you have received this facsimile in error, please immediately notify us by telephone to arrange for return of the original documents to us; and any disclosure, copying, distribution or the taking of any action in reliance on the contents of this faxed information is strictly prohibited.

TO: Leon Yan Bon Lum  
FIRM: U.S. P.T.O.  
FACSIMILE NO.: 703-872-9306  
OUR REF.: NAGACO.005A  
YOUR REF.: Appl. No. 09/988,728  
FROM: Drew S. Hamilton  
OPERATOR: Michelle Tow  
DATE: May 2, 2005

NO. OF PAGES: 7 (incl. cover sheet)  
TIME:

**IF YOU DID NOT RECEIVE ALL OF THE PAGES PLEASE CALL BACK IMMEDIATELY**

OPERATOR PHONE No.: (619) 235-8550

FACSIMILE No.: (619) 235-0176

**MESSAGE:**

1687289  
042805

Orange County  
949-760-0404

San Francisco  
415-954-4114

Los Angeles  
310-551-3450

Riverside  
951-781-9231

San Luis Obispo  
805-547-5580

PTOL-413A (08-03)

Approved for use through 07/31/2006. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

## Applicant Initiated Interview Request Form

Application No.: 09/988728 First Named Applicant: Gowri Pyapal Selvan  
 Examiner: Leon Yan Bon Lum Art Unit: 1641 Status of Application: \_\_\_\_\_

## Tentative Participants:

(1) Drew S. Hamilton (2) Cort Wetherald  
 (3) \_\_\_\_\_ (4) \_\_\_\_\_

Proposed Date of Interview: 5/3/05 Proposed Time: 9:00 (AM/PM)

## Type of Interview Requested:

(1) ☐ Telephonic (2) ☒ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☐ YES ☒ NO

If yes, provide brief description: \_\_\_\_\_

## Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>Rej.</u>	<u>1</u>	<u>Sheppard, Jr.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) <u>Rej.</u>	<u>1</u>	<u>Sizto, et al.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☒ Continuation Sheet Attached Please see attached set of proposed claims.

## Brief Description of Arguments to be Presented:

The claims are patentable over the art of record since, for example, the acts of "generating a trigger signal", "generating an output signal", process and generating a count are neither taught nor suggested by the prior art.

An interview was conducted on the above-identified application on \_\_\_\_\_.

## NOTE:

This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

[Signature]  
 (Applicant/Applicant's Representative Signature)

\_\_\_\_\_  
 (Examiner/SPE Signature)

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 C.F.R. 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22311-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**NAGACO.005A**  
**CLAIMS For Discussion, 5/2/05**  
**NOT FOR ENTRY IN THE RECORD**

**METHODS AND APPARATUS FOR DETECTING AND QUANTIFYING  
LYMPHOCYTES WITH OPTICAL BIODISCS**

App No: 09/988,728  
Inventor: Gowri K. Pyapali

Filing Date: 16 Nov 01

1. (Currently Amended) A method of conducting an assay, the method comprising:
  - providing a sample of cells in a chamber in a disc, the chamber including at least one capture zone with a capture agent, the disc including at least one inlet port and a vent port on a first surface of the disc;
  - loading the disc into an optical reader;
  - rotating the disc so as to separate different cell types into different capture zones;
  - directing an incident beam of electromagnetic radiation to the at least one capture zone so as to capture cells in the at least one capture zone;
  - detecting at least one beam of electromagnetic radiation formed after interacting with the disc at the capture zone;
  - generating a trigger signal in response to trigger information contained in the at least one beam;
  - converting-generating an output signal indicative of at least a portion of the detected at least one beam into an output signal relating to the captured cells;
  - processing at least a portion of the output signal in response to the trigger signal;and
  - analyzing the at least a portion of the output signal to extract therefrom information relating to the number of cells captured at the at least one capture zone;
  - generating a counting of captured-the number of cells in each of the at least one capture zones; and
  - providing an output including the counts, ~~wherein the output includes counts for CD4 cells and CD8 cells.~~
2. (Previously Presented) The method according to claim 1, wherein the chamber is internal to the disc and is bounded on opposite sides by a substrate and cap.

**NAGACO.005A**  
**CLAIMS For Discussion 5/2/05**  
**NOT FOR ENTRY IN THE RECORD**

**METHODS AND APPARATUS FOR DETECTING AND QUANTIFYING**  
**LYMPHOCYTES WITH OPTICAL BIODISCS**

App No: 09/988,728  
Inventor: Gowri K. Pyapali

Filing Date: 16 Nov 01

- 
3. (Original) The method according to claim 1, wherein the optical disc is constructed with a reflective layer such that light directed to the capture zone and not striking a cell is reflected.
  4. (Previously Presented) The method according to claim 1, wherein the optical disc is constructed such that light directed to the capture zone and not striking a cell is transmitted through the optical disc, the disc being between the light source and the a detector.
  5. (Previously Presented) The method according to any one of claims 1-5, wherein the disc surface is coated with a first group of cell capture agents.
  6. (Previously Presented) The method according to claim 5, wherein the cell capture agents define a capture zone.
  7. (Currently Amended) The method according to claim 6, wherein a second group of cell capture agents define a second capture zone.
  8. (Original) The method according to claim 7, wherein the first and second captures zones are in one chamber.
  9. (Original) The method according to claim 5, wherein the cell capture agents are for binding with cell surface antigen.

**NAGACO.005A**  
**CLAIMS For Discussion 5/2/05**  
**NOT FOR ENTRY IN THE RECORD**

**METHODS AND APPARATUS FOR DETECTING AND QUANTIFYING**  
**LYMPHOCYTES WITH OPTICAL BIODISCS**

App No: 09/988,728  
Inventor: Gowri K. Pyapali

Filing Date: 16 Nov 01

- 
10. (Original) The method according to claim 9, wherein the cell surface antigen is selected from the CD family of antigens.
11. (Original) The method according to claim 10, wherein the cell surface antigen is selected from the group consisting of CD3, CD4, CD3, and CD45.
12. (Original) The method according to claim 1, further including:  
directing the sample of cells into proximity with the cell capture agents;  
incubating the cells in the presence of the capture agents; and  
allowing the cells to specifically bind to the capture agents.
13. (Original) The method according to claim 12, further including analyzing the number of cells captured to thereby determine a cell concentration in the sample.
14. (Previously Presented) The method of claim 13, wherein the analyzing includes detecting sufficiently large changes in a level of light reflected from or transmitted through the disc.
15. (Original) The method of claim 13, wherein the analyzing includes using image recognition to count captured cells.
16. (Previously Presented) The method of claim 15, wherein the image recognition distinguishes one type of white blood cell from another.

**NAGACO.005A**  
**CLAIMS For Discussion 5/2/05**  
**NOT FOR ENTRY IN THE RECORD**

**METHODS AND APPARATUS FOR DETECTING AND QUANTIFYING**  
**LYMPHOCYTES WITH OPTICAL BIODISCS**

App No: 09/988,728  
Inventor: Gowri K. Pyapalli

Filing Date: 16 Nov 01

- 
17. (Original) The method of claim 1, wherein the chamber has a plurality of capture zones, each having a different cell capture agent.
18. (Previously Presented) The method of claim 17, wherein the rotating includes rotating for a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with the capture moleculesagents.
19. (Original) The method of claim 18, wherein the rotating includes rotating for a sufficient period of time at a sufficient speed so that unbound cells are moved away from the capture zones.
20. (Original) The method of claim 19, wherein the rotating is done at a single speed.
21. (Original) The method of claim 17, further comprising counting the captured cells in each of the capture zones and providing an output including the counts.
22. (Previously Presented) The method of claim 21, wherein the output includes a ratio of CD4 to CD8 cells.
- 23-29. Cancelled.
30. (Previously Presented) The method of claim 12, wherein the analyzing includes detecting sufficiently large changes in the level of light reflected from or transmitted through the disc.

**NAGACO.005A**  
**CLAIMS For Discussion 5/2/05**  
**NOT FOR ENTRY IN THE RECORD**

**METHODS AND APPARATUS FOR DETECTING AND QUANTIFYING  
LYMPHOCYTES WITH OPTICAL BIODISCS**

App No: 09/988,728  
Inventor: Gowri K. Pyapali

Filing Date: 16 Nov 01

31. (Previously Presented) The method of claim 12, wherein the analyzing includes using image recognition to count captured cells.

32. (~~New~~Currently Amended) The method of Claim 1, wherein the disc comprises a first layer of ~~strepatavidin~~streptavidin, a first antibody raised in a first species against a type of immunoglobulin of a second species, and a second antibody raised in the second species against a cell surface antigen.

33. (New) The method of Claim 1, wherein each of the capture zones are sequentially located in a fluid path between the inlet port and the vent port, and wherein capture zones are sequentially provided for CD4, CD8 and a control in relation to the fluid path.

34. (New) The method of Claim 1, wherein the at least one beam comprises a first beam for detecting the trigger information and a second beam for interacting with the disc at the at least one capture zone.

1688923  
042905 LMT